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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,

Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF THE PETITIONER

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QUESTION PRESENTED

Does the Federal Food, Drug, and Cosmetic Act of 1938 authorize the Food and Drug Administration to determine, through exercise of its administrative discretion, whether to regulate added poisonous or deleterious substances in the food supply by (1) establishing informal "action levels" that constitute criteria for determining when the FDA will initiate court enforcement proceedings under Section 402(a)(1) of the Act, without (2) establishing formal "tolerances" through rulemaking on a record under Section 406 of the Act that constitute substantive requirements under the Act?

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INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc. (GMA), is a trade association representing companies that manufacture food products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of GMA ship products in interstate commerce for sale throughout the country and thus are subject to all of the requirements established under the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C

Act)[1] relating to food safety. GMA and its members therefore have a major interest in assuring that regulatory requirements relating to food safety conform to the provisions of the FD&C Act and impose no more burdensome procedural or substantive requirements than are reasonably necessary to maintain compliance with the Act. GMA and its members strongly support the current Food and Drug Administration (FDA) approach to regulating added poisonous or deleterious substances in the food supply under the FD&C Act, but oppose changes that would be required by the decision of the United States Court of Appeals for the District of Columbia Circuit[2] in this case.[3]

SUMMARY OF ARGUMENT

Under the Food and Drugs Act of 1906, FDA was given enforcement discretion to take regulatory action against any added poisonous or deleterious food ingredient which may render the food injurious to health. In construing this general food safety standard in the *Lexington Mill* case in 1914, this Court determined that it was intended to prohibit any substance that represented a reasonable possibility of harm to human health under actual conditions of use.

When Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 to replace the 1906 Act, it purposely retained the same wording in Section 402(a)(1) in order to retain the interpretation adopted in *Lexington Mill*. At the same time, Congress realized that not all added poisonous or deleterious substances can or should be prohibited. Accordingly, Section 406 was included in the 1938 Act specifically to authorize FDA to set tolerances for added poisonous or deleterious substances that would otherwise

[1] 52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[2] Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

[3] All parties have consented to the filing of this brief by letters that have been filed with the clerk of the court in accordance with Rule 36.

be banned under Section 402(a)(1), where those substances are either "required in the production" of food or "cannot be avoided by good manufacturing practice."

In the legislative history, Congress used three types of examples to illustrate the categories of substances to which Section 406 was intended to apply. First, Section 406 was intended to apply to pesticide residues in food, where the pesticide is necessary to produce the food. Second, Section 406 was intended to apply to a functional food additive, such as a preservative added to prevent rancidity, where it is necessary for the production of the food. Third, Section 406 was intended to apply where a raw material contained a contaminant that could not entirely be eliminated by purification processes, and thus cannot be avoided in good manufacturing practice. When Congress subsequently enacted the Miller Pesticide Amendment in 1954 and the Food Additives Amendment of 1958, more specifically to govern pesticide residues and food additives, Section 406 was nonetheless retained to permit FDA to continue to handle pesticide residues, food additives, and contaminants, under Section 406 as well.

In order to maximize public health protection, FDA has taken an extremely broad interpretation of the scope of the statutory term, "added substance." Under current FDA interpretation, virtually all food substances are regarded as added. With the extraordinary advances since 1938 in science generally, and in analytical chemistry and toxicology in particular, it is now apparent that the food supply contains literally hundreds of added substances that would be considered poisonous or deleterious under extreme conditions but that do not represent a reasonable possibility of harm to human health under actual conditions of human use. FDA now recognizes, for example, that virtually all food contains inherent carcinogenic ingredients or carcinogenic contaminants. As more and more natural food substances are tested, more are found to be carcinogenic or otherwise toxic under some conditions of stringent laboratory testing and experimentation. It is thus apparent that, because of new scientific knowledge, FDA

can identify added poisonous or deleterious substances in every food product marketed in the country today.

To handle this problem, FDA has adopted a very responsible and reasonable regulatory approach. For those poisonous or deleterious substances that do not represent a significant risk, FDA has simply ignored their presence and has not established either an informal action level or a formal tolerance. For those that the Agency has found at levels that could potentially raise public health concern, action levels have been established, and specific regulatory action has been taken, to make certain that they represent no reasonable possibility of harm to human health. In one instance, where there was persistent controversy and litigation, the Agency established a formal tolerance on the basis of a rulemaking on a record.

This system has worked well to protect the American public health. It reflects the congressional intent to retain FDA's discretion to bring enforcement action under Section 402(a)(1), based on the *Lexington Mill* standard.

The court of appeals in the instant case held that a formal tolerance must be promulgated for every added poisonous or deleterious substance in the food supply. It is clear that the court of appeals did not understand the implications of its holding. Such a task would overwhelm FDA. It is contrary to the legislative history, to the statutory purpose of Section 406, and to common sense and good government. If FDA were to devote all of its resources to such a task, it is unlikely that it could be accomplished in the foreseeable future. Thus, under the decision of the court of appeals, virtually the entire United States food supply would remain unlawful for decades to come. Such an implausible result could hardly have been intended by Congress and should be rejected by this Court.

ARGUMENT

I. Congress Intended FDA to Have Discretionary Authority to Regulate Added Poisonous or Deleterious Substances Either by Court Enforcement Proceedings Under Section 402(a)(1) or by Rulemaking Under Section 406.

A. Under the 1906 Act, FDA Had Authority to Regulate Added Poisonous or Deleterious Ingredients by Court Enforcement Proceedings.

In 1906, when the first national food safety legislation was enacted,[4] Congress declared that a food was adulterated, and thus illegal, if it contained:

> ". . . any added poisonous or other added deleterious ingredient which may render such article injurious to health . . ."[5]

In construing this statutory prohibition in the *Lexington Mill* case in 1914,[6] the Supreme Court rejected both the argument made by industry on the one extreme that food could be condemned only if it was shown actually to injure health, and the argument made by the government on the other extreme that food must be condemned if it contained even a harmless amount of a substance that would be poisonous or deleterious at a higher level:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the

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[4]Food and Drugs Act of 1906, 34 Stat. 768 (1906).

[5]Section 7, 34 Stat. at 770.

[6]United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).

added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb, qualifying the meaning of another verb, by expressing ability . . . contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."[7]

Thus, this Court took the very reasonable intermediate position that an added poisonous or deleterious substance violated the law if it represented a reasonable possibility of harm to human health under its actual conditions of use.

The scope of the statutory reference to an "added" ingredient under the 1906 Act was also the subject of review by this Court, in the *Coca Cola* case in 1916.[8] The

[7] *Id.* at 411. This Court has, more recently, adopted virtually an identical interpretation in requiring the finding of a significant human risk before regulation may be imposed under the Occupational Safety and Health Act. Industrial Union Dept, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

[8] United States v. Coca Cola Co., 241 U.S. 265 (1916).

Court held that a food substance must be regarded as "added" if it was "artificially introduced," whether the addition was "made to a natural food product or to a compound."[9] Indeed, the Court commented that Congress may have supposed "that, ordinarily, familiar food bases would be used for this purpose."[10] This interpretation allowed FDA to pursue a broad and expansive interpretation of the term "added," that the agency has continued to this day.

B. Section 402(a)(1) of the 1938 Act Was Intended to Continue the Lexington Mill Decision.

When Congress enacted the 1938 Act to replace the 1906 Act, it retained, in Section 402(a)(1), the prohibition against any "added substance" in food that is a "poisonous or deleterious substance which may render it injurious to health."[11] The legislative history makes it clear that, although this provision was slightly reworded to fit the context of the new statute, Congress intended to retain the substance and this Court's interpretation of the 1906 Act provision. The Chief of the FDA, W.G. Campbell, testified before Congress in 1934 that the language of the provision in the pending legislation that became the 1938 Act:

> ". . . is the language of the present law. That language has been considered in litigation which was carried to the Supreme Court, and has been exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which

[9] *Id.* at 284.

[10] *Id.*

[11] Section 402(a)(1) of the FD&C Act, 21 U.S.C. § 342(a)(1).

> has already been considered by the Supreme Court."[12]

The committee reports in the Senate, which exercised the lead role in this legislation, reflected this intent of the draftsmen.[13] In fact, this Court has since recognized that its 1914 decision remains the controlling construction of the 1938 Act as well.

> "The language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)."[14]

Thus, Congress intended that the authority of FDA to enforce the statutory prohibition against added poisonous or deleterious substances would remain the same under the 1938 Act as under the 1906 Act.

C. Section 406 of the 1938 Act Was Intended to Authorize FDA to Permit the Continued Use of Added Substances That Would Otherwise Violate Section 402(a)(1).

Between 1906 and 1938, Congress realized that not all added poisonous or deleterious substances that may render food injurious to health can or should be prohibited. Some are vitally needed to produce an adequate supply of food at reasonable cost, and others are unavoidable contaminants. Accordingly, the 1938 Act included, for the first time, a provision, Section 406,[15] authorizing FDA to set tolerances for added poisonous or deleterious substances that would otherwise be banned under Section 402(a)(1) where those substances either are "required in the production" of food or "cannot be avoided by good manu-

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[12]"Foods, Drugs, and Cosmetics," Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess. 530 (1934).

[13]S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935).

[14]Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958). *See, e.g.*, United States v. 2,116 Boxes of Boned Beef, Food Drug Cosm. L. Rep. (CCH) ¶ 38,114 (D. Kan. 1981).

[15]21 U.S.C. § 346.

facturing practice."[16] Under either of these circumstances, FDA was given the authority to set formal tolerances, after rulemaking on a record, to establish whatever limitations are necessary for the protection of the public health. This authority was intended to be in addition to, and in no way to detract from, the pre-existing prohibition against added poisonous or deleterious substances that was retained in Section 402(a)(1).

In enacting Section 406, Congress did not define the critical terms "required in the production" or "cannot be avoided." The legislative history does, however, give a number of important examples of the broad and comprehensive application intended for Section 406. From its inception, it is apparent from these examples that Congress intended Section 406 to be potentially available for any added poisonous or deleterious substance, whether it was directly and intentionally added or indirectly and unintentionally added.

The initial legislation considered by Congress only contained the "required in the production" portion of the criteria that were ultimately included in Section 406. The 1934 Senate report explained this portion of Section 406:

> "Section 10(a) authorizes the Secretary to promulgate regulations for any added poison in food and cosmetics, or to establish tolerances limiting the amount. In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances

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[16]For such a substance, Section 402(a)(2)(A), 21 U.S.C § 342(a)(2)(A), provides that the failure to comply with a promulgated tolerance renders the food adulterated and thus unlawful.

for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to every [sic] small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product.

In approaching the problem of control from this angle the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health."[17]

It is clear from the two examples used in this passage that the Senate intended the "required in the production" language to include direct and intentional addition of a poisonous or deleterious substance to food. The pesticides to which the report referred were sprayed directly on the food. The maleic acid to which the report referred was added directly and intentionally to preserve the food.[18]

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[17]S. Rep. No. 493, 73d Cong., 2d Sess. 4 (1934).

[18]There would have been no purpose in referring to the maleic acid example if Congress had not intended Section 406 potentially to be available for direct and intentional additives. The maleic acid example was used to show that, where a reasonably practicable alternative was available, the additive could not meet the "required" standard established by the provision. Where a method of food preservation is determined to be necessary, such as the use of lead in food canning, FDA has concluded that the "required" standard could be met. 44 Fed. Reg. 51233, 51240 (August 31, 1979).

Subsequently, the "cannot be avoided" portion was added to this provision. The new language was explained in the 1935 Senate report:

> "Section 304(a) prohibits the addition of poisonous or deleterious substances to food except where such addition is required in production, as in the case of poisonous sprays for fruits and vegetables to protect them against insects or fungus diseases, or where such addition cannot be avoided in good manufacturing practice, as where purification processes cannot entirely eliminate a contaminant of raw materials, or where some contaminant is unavoidably introduced in factory operations. This section then authorizes the establishment of tolerances for the protection of public health in those instances where the addition of the poison is required or cannot be avoided. In determining tolerances for different articles of food there must be taken into account the extent to which the poison is required or cannot be avoided and likewise the other ways in which the consumer may be affected by the same or other poisonous substances. The prohibition of added poisons by this section will control those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add toxic substances to food, as, for example, maleic acid to fats or oils to prevent rancidity when the preservation can be accomplished by observance of sanitary conditions in manufacturing and packaging."[19]

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[19]S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935). The substitute report filed later in the year shortened the description but did not change its substance. S. Rep. No. 646, 74th Cong., 1st Sess. 3 (1935). Neither the minority views expressed with respect to the earlier report nor any aspect of the legislative history between the two reports reflected any disagreement with this portion of the legislation or the earlier report.

The example given by the Senate, in this report, of a substance that "cannot be avoided" was a food contaminant that could not be eliminated by processing. The report also continued to use a directly applied pesticide as an example of an added poisonous or deleterious substance that is "required in the production" of food. The final Senate report, filed in 1937, contained only a brief reference to Section 406.[20]

The House report in 1938 contained basically the same description as had the earlier Senate reports.[21] Once again the direct and intentional addition of pesticides to raw agricultural commodities was given as an example of an added poisonous or deleterious substance that is "required in the production" of food. It was this version of the legislation that was passed by Congress and signed into law.

In 1954, Congress enacted the Miller Pesticide Amendment, adding Section 408 to the FD&C Act to provide additional authority to regulate the direct and intentional addition of pesticides to raw agricultural commodities.[22] Pesticide residues were, of course, one of the two examples given by Congress of the potential use of the "required in the production" portion of Section 406. Nonetheless, Congress did not conclude during the consideration of the 1954 Amendment that the "required in the production" portion of Section 406 was now obsolete or should be limited or otherwise modified. If that portion of Section 406 had indeed been intended by Congress no longer to be available for use in handling the direct and intentional addition of pesticides to food, Congress would have repealed or revised that portion of Section 406. Instead, Section 406 was left intact.

Four years later, Congress enacted the Food Additives Amendment of 1958 to provide additional authority to reg-

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[20]S. Rep. No. 91, 75th Cong., 1st Sess. 5 (1937).

[21]H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938).

[22]68 Stat. 511 (1954), 21 U.S.C. § 346a.

ulate those substances that are directly and intentionally added to the food supply either directly or indirectly.[23] Once again, Congress did not decide that, upon enactment of the 1958 Amendment, the "required in the production" portion of Section 406 would become obsolete and inoperative. No one recommended repeal or revision of that portion of Section 406, and in fact it was not changed in any way. And no further relevant changes have been made in the FD&C Act since then. Thus, Section 406 has not been amended since it was enacted in 1938.

II. FDA Has Consistently Interpreted and Applied Section 402(a)(1) and Section 406 as Separate Enforcement Provisions.

A. Under Current FDA Interpretation Of The FD&C Act, Virtually All Food Substances Are Regarded As Added Substances.

Under the FD&C Act, food substances are divided into two basic categories: (1) added and (2) non-added. Non-added substances may lawfully be used as food if they are not "ordinarily injurious to health" pursuant to Section 402(a)(1).[24] Added substances are unlawful under Section 402(a)(1) if they "may render [the food] injurious to health." Under the Food Additives Amendment of 1958, added substances that meet the definition of a "food additive" in Section 201(s) of the FD&C Act may be used in food only after FDA has approved them as "safe" in accordance with the provisions of Section 409.[25]

Because the statute imposes a lighter burden on FDA for regulating added substances, FDA has pursued an expansive interpretation of the term "added" and has viewed the "non-added" category as extremely limited and narrow in scope. FDA has stated that a "naturally occurring"

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[23]72 Stat. 1784 (1958), 21 U.S.C. § 348.

[24]United States v. 1232 Cases American Beauty Brand Oysters, 43 F. Supp. 749 (W.D. Mo. 1942).

[25]21 U.S.C. § 321(s) and § 348.

substance is not an added substance,[26] but has narrowly defined a "naturally occurring" substance as a:

> ". . . substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination."[27]

In explaining these definitions, FDA emphasized that any substance that is "not inherently a component of the food" would be regarded as added, and rejected contentions that added substances are only those that occur in food as a result of some human action.[28]

FDA has pursued this interpretation vigorously in the courts. FDA has successfully argued that salmonella is an added substance in eggs[29] and shrimp,[30] aflatoxin is an added substance in corn,[31] DDT is an added substance in fish,[32] and lead migrating from pottery plates is an added substance in food.[33]

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[26]21 C.F.R. § 109.3(d).

[27]21 C.F.R. § 109.3(c).

[28]39 Fed. Reg. 42743, 42744 (December 6, 1974); 42 Fed. Reg. 52814 (September 30, 1977).

[29]United States v. 1200 Cans, Pasteurized Whole Eggs, 339 F. Supp. 131 (N.D. Ga. 1972).

[30]Seabrook International Foods, Inc. v. Harris, 501 F. Supp. 1086 (D.D.C. 1980).

[31]United States v. 1,680,000 Pounds of White Corn, Civil No. T-4173 (D. Kan., December 18, 1970), *in* V. Kleinfeld et al., Federal Food, Drug, and Cosmetic Act Judicial Record 1969-1974,at 214 (1976); United States v. Boston Farm Center, Inc., 590 F.2d 149 (5th Cir. 1979).

[32]United States v. Ewig Bros. Co., Inc., 502 F.2d 715 (7th Cir. 1974).

[33]United States v. Articles of Food . . . Pottery, 370 F. Supp. 371 (E.D. Mich. 1974). The courts have split on the question whether mercury is an added substance in fish. *Compare* United States v. An Article of Food Consisting of Cartons of Swordfish, 395 F. Supp. 1184 (S.D.N.Y. 1975) *with* United States v. Anderson Seafoods, Inc., 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980). *See also* Note, Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish, 85 Harv. L. Rev. 1025 (1972).

The broad sweep of FDA's interpretation of the scope of the term "added" is apparent from the agency's lists of food additives, all of which are necessarily added substances. FDA has unequivocally stated that "Neither that language [in 21 U.S.C. § 321(s)] nor the legislative history of the Food Additives Amendment reveals an intent to exclude natural food constituents from regulation as food additives."[34] Just before enactment of the Food Additives Amendment of 1958, FDA submitted a list of illustrative "chemical food additives" to the House of Representatives that included brandy, butter, coffee, corn oil, cream, dried skim milk, lard, lemon juice, mace, margarine, molasses, mustard, olive oil, pepper, salt, sugar, vinegar, and wine.[35]

FDA has thus far delineated no limit to the concept of an "added" substance, other than excluding the inherent natural constituents of a raw agricultural commodity that is marketed and consumed without further processing or

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[34]41 Fed. Reg. 19207, 19208 (May 11, 1976).

[35]"Food Additives," Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 85th Cong., 2d Sess. 461-462 (1958). FDA Commissioner Edwards testified in 1972 that the term "food additive":

> ". . . is not limited to the artificial or synthetic chemicals that the public most often associates with it. It includes all raw agricultural commodities as well as fabricated food. This means that, for example, the components of beef stew—the carrots and meat, as well as any emulsifiers or stabilizers—must either be classified as GRAS or must be subject to a food additive regulation promulgated by the Commissioner.
>
> The components of butter and ice cream, both of which are fabricated foods, must all be classified as GRAS or be the subject of a promulgated regulation.
>
> In essence, under modern methods of processing and packaging, virtually the entire food supply must be classified either as GRAS or as regulated food additives, or they may not lawfully be permitted to be used as part of the daily diet."

"Nutrition and Human Needs," Hearings before the Select Committee on Nutrition and Human Needs, United States Senate, 92d Cong., 2d Sess., Pt 4B, at 1199, 1201 (1973).

preparation. As soon as any processing or preparation is undertaken, consistent with judicial precedent beginning with the *Coca Cola* decision and extending to the present, FDA has taken the position that the raw agricultural commodity and every other substance used in making the processed food are all added substances that must individually withstand scrutiny under the provisions of Section 402(a)(1).

B. The Food Supply Contains Hundreds of Added Substances That Would be Considered Poisonous or Deleterious Under Extreme Conditions but That Do Not Represent a Reasonable Possibility of Harm to Human Health Under Actual Conditions of Human Use.

Throughout history, the food supply has always consisted of natural food items and of functional ingredients added in the course of food production and processing. As part of the industrial revolution, our large urban centers developed, and people no longer grew their own food. Dramatic changes were needed in food production, transportation, processing, packaging, and preservation in order to accommodate this new national lifestyle. Society increasingly depended upon chemicals of both natural and synthetic origin to serve these purposes, and the number and frequency of these substances in the food supply—both as functional additives and as environmental contaminants—therefore inevitably increased. Our food supply has been estimated to consist of more than 13,000 known direct and indirect constituents and an untold number of additional environmental contaminants.[36]

Although these added substances have always been present, they have not always been detectable by the scientific methodology available to analytical chemists. At the beginning of this century, for example, when the 1906 Act was enacted, analytical methodology was basically qualitative rather than quantitative in nature and in some re-

[36]"Food Additives: Competitive, Regulatory, and Safety Problems," Hearings before the Select Committee on Small Business, United States Senate, 95th Cong., 1st Sess. 42, 52, 57, 502-503 (1977).

spects had advanced very little beyond what was known and practiced in ancient Greece and Rome.[37] By the time that the 1938 Act was passed, analytical methodology had become more quantitative in nature, but was accurate only at relatively high levels. When the Food Additives Amendment of 1958[38] was enacted, the sensitivity of detection methodology had been reduced to the relatively high parts per million (ppm) level. During the past 30 years, it has progressively been reduced first to the very low ppm level, then to parts per billion (ppb) and parts per trillion (ppt), and now to parts per quadrillion (ppq).[39] In a preamble to a proposed regulation published by FDA in 1979, the agency described this:

> ". . . trend of the increasing capacity of analytical chemistry to detect [and] measure the presence of chemicals. Depending on the substance or class of substances this decrease in the lowest limits of measurement during the last 20 years ranges between two and five orders of magnitude [*i.e.*, between 100 and 100,000 times]."[40]

It is helpful, in appreciating the significance of these levels, to realize that one ppb, which is now commonplace for all detection methodology, is equivalent to one second in 32 years or one inch in 16,000 miles.

With every incremental advance in the science of analytical chemistry, more and more added substances have

[37]Browne, "Adulteration and the Condition of Analytical Chemistry Among the Ancients," 29 Science 455 (March 19, 1909). Dr. Browne served as President of the Association of Official Analytical Chemists in 1925 and as Commissioner of Food and Drugs during 1923-1927.

[38]72 Stat. 1784 (1958).

[39]*E.g.*, Richardson et al., Sub-Part-Per-Trillion Detection of Riboflavin by Laser-Induced Fluorescence, 86 Analytica Chimica Acta 263 (1976).

[40]44 Fed. Reg. 17070, 17075 (March 20, 1979). The notice included tables showing the increased sensitivity of the analytical detection methodology for specific chemicals. *Id.* at 17076-17077.

been found at trace levels in the American food supply. Most, if not all, of these added substances would be regarded as poisonous or deleterious under extreme conditions of use, but pose no reasonable possibility of harm to human health under their actual conditions of use. Poisonous or deleterious substances that could not be found at the ppm level can often be found at the ppb or ppt level, and are even more certain to be found at the ppq level. Although it appeared in 1938, when Section 406 was enacted, that there were relatively few added poisonous or deleterious substances to be found in food, it is now apparent that there are literally hundreds of them.

For example, FDA now recognizes that carcinogens are ubiquitous in our environment and that it is impossible to attain a carcinogen-free supply of food. As early as 1971, FDA stated that carcinogenic estrogens occur naturally in many raw agricultural commodities.[41] In 1979, FDA determined that a cancer warning on the label of all food containing a carcinogen might be "impractical and confusing" because:

> ". . . a requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket."[42]

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[41] "Regulation of Diethylstilbestrol (DES)," Hearings before a Subcommittee of the Committee on Government Operations, House of Representatives, 92d Cong., 1st Sess., Pts 1 & 2 (1972).

[42] 44 Fed. Reg. 59509, 59513 (October 16, 1979). Officials of the FDA's Center for Food Safety and Applied Nutrition, writing about the added carcinogenic substances in food, have noted "the carcinogenic hazards from corn, peanuts, milk, grain, canned food, hamburger, poultry, beef, fish, hot dogs, and even scotch and beer" and have stated that "the spectrum of natural carcinogenic contaminants at low levels in food" is very large. Scheuplein et al., New Approaches to the Regulation of Carcinogens in Food: The Food and Drug Administration, *in* H.A. Millman & E.K. Weisburger, Handbook of Carcinogen Testing 556, 561, 565 (1985).

As one example, the National Toxicology Program of the Department of HHS announced in 1983 that allyl isothiocyanate, which was shown to be a carcinogen, is:

> ". . . the major component in volatile oil of mustard, a flavoring agent prepared from seed of black mustard.
>
> Allyl isothiocyanate may be present in syrups, meats, condiments, baked goods, candy, ice cream and ices, and non-alcoholic beverages. Allyl isothiocyanate is found in cabbage, broccoli, kale, cauliflower and horseradish."[43]

Numerous dietary carcinogens in the natural food supply—including herbs, spices, and essential vitamins and minerals—have been identified in the scientific literature.[44] None of these can be disregarded by FDA either as not added or as not poisonous or deleterious.

C. FDA Has Rationally and Reasonably Applied the Statute to Regulate Added Poisonous or Deleterious Substances.

Were it not for the statutory interpretation of the food safety provisions of the FD&C Act adopted and consistently applied by FDA, this would have become a regulatory nightmare for FDA, the food industry, and the public. As more and more added poisonous or deleterious substances are found, reasonable decisions must be made by FDA on how best to handle them in order to assure a safe food supply for the American public.

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[43] 48 Fed. Reg. 4557 (February 1, 1983).

[44] *E.g.*, Ames, Dietary Carcinogens and Anticarcinogens, 221 Science 1256 (September 23, 1983); Campbell, Web of Hunger: More is Not Necessarily Better, 90 Natural History, no. 5, at 12 (May 1981); Miller et al., eds., Naturally Occurring Carcinogens-Mutagens and Modulators of Carcinogenesis (1979); Rodricks & Pohland, Food Hazards of Natural Origin, *in* H. Roberts, ed., Food Safety 181 (1981); National Academy of Sciences, Toxicants Occurring Naturally in Food (2d ed. 1973); Weisburger, Carcinogenic Natural Products, *in* Food and Drug Administration, Symposium on Structural Correlates of Carcinogenesis and Mutagenesis 184 (1977).

Until the early 1970s, the potential magnitude of this problem was not appreciated. By 1974, FDA realized that it could no longer ignore the growing number of added poisonous or deleterious substances that are required or unavoidable in the food supply, and thus for the first time proposed procedural regulations to implement Section 406.[45] In the explanatory preamble, FDA first set out the expansive interpretation of the term "added" that it has always espoused. The preamble concluded that enactment of the Food Additives Amendment of 1958 neither explicitly nor implicitly excluded food additives from the scope of Section 406:

> "When the Food Additives Amendment of 1958 was enacted, the provisions of section 406 of the act were not repealed. Although all added poisonous or deleterious ingredients are food additives, except when they appear in food accidentally and unforeseeably or are exempted under section 201(s) of the act because they are otherwise regulated under the act, the tolerance-setting provisions of section 406 of the act were left intact to deal with those unavoidably added poisonous or deleterious ingredients that could not meet the high standards for issuance of a regulation under the authority of section 409 of the act."[46]

As FDA recognized, a number of food additives that cannot meet the "high standards" of Section 409 might nonetheless be required or unavoidable in food.[47]

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[45]39 Fed. Reg. 42743 (December 6, 1974).

[46]*Id.* at 42744.

[47]The safety standards in Section 402(a)(1) and Section 409 are indistinguishable. Section 402(a)(1) has been interpreted by this Court to embody the standard of a "reasonable possibility of harm." Section 409, as explained in the legislative history that has been adopted by FDA as the definitive statement of the 1958 Amendment, embodies a standard of "reasonable certainty [of] no harm." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958). The 1958 Amendment thus transfered the burden of proving safety from the government to the regulated industry, but did not change the safety standard itself.

In response to the proposed regulation, FDA received one comment questioning the authority for Section 406 tolerances for food additives under the "cannot be avoided" portion of Section 406. The preamble to the final regulations,[48] promulgated in 1977, agreed that an intentional food additive was usually avoidable, but did not agree that such an additive could not meet the "required in the production" portion of Section 406. FDA emphasized the distinction between these two portions of Section 406 in rejecting a comment that had argued that the term "added" should be narrowly interpreted to apply only to human activity:

> "The Commissioner notes that the comment discussed only the initial portion of section 406 of the act. The section goes on to identify two circumstances in which 'added' poisonous or deleterious substances may be permitted: (1) Where the substance is 'required in the production' of a food, and (2) or where the substance 'cannot be avoided by good manufacturing practice.' Although the language of the first circumstance connotes human action, the language of the second does not."[49]

The final regulations promulgated by FDA in 1977 explicitly dealt only with added poisonous or deleterious substances that fall within the "cannot be avoided" portion of Section 406, and did not deal at all with those that fall within the "required in the production" portion of Section 406.[50] Similarly, the instant case involves only the former and not the latter. In 1979, FDA determined that a deliberately added poisonous or deleterious substance (lead

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[48]42 Fed. Reg. 52814 (September 30, 1977).

[49]*Id.*

[50]21 C.F.R. pt 109.

in food canning) could be encompassed within the "required in the production" portion of Section 406.[51]

Under the FDA regulatory approach that has prevailed for the past half century, control of all added poisonous or deleterious substances has proved to be a manageable task. For those added poisonous or deleterious substances that represent an insignificant risk—whether they are "required in the production" of food or "cannot be avoided"—FDA simply ignores their presence and does not establish either an informal action level or a formal tolerance. For those that are required in food production and that are found at levels that could potentially raise public health concern, regulatory controls under Sections 402(a)(1), 408, and 409 have been sufficient to protect the public health. For those that are unavoidable and that are found at levels that could potentially raise public health concern, action levels (shown in Appendix A) have been established to make certain that they represent no reasonable possibility of harm to human health. As more has become known about those substances (and their toxicity and level of human exposure), those action levels have been changed over time. In the one instance where sufficient data have accumulated to permit a permanent maximum level, and persistent litigation justified the time and expense involved in the administrative proceeding, a formal tolerance has been promulgated on the basis of a rulemaking on a record.[52]

This approach is sensible and has in fact worked very well to protect the health of the American public. FDA has established conservative levels for added poisonous or deleterious substances and in fact no human toxicity has been traced to them.

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[51] 44 Fed. Reg. 51233, 51240 (August 31, 1979).

[52] 21 C.F.R. § 109.30 (polychlorinated biphenyls).

III. The Decision of the Court of Appeals Would Impose a Burdensome and Unreasonable Regulatory Scheme Without Any Public Health Benefit.

In place of the existing common sense approach that has prevailed for the past 50 years, the court of appeals would arbitrarily require an expensive and time-consuming new scheme that would serve no public health purpose. The novel interpretation advanced by the court of appeals would require the formal establishment of a tolerance under Section 406, based upon rulemaking on a record, for every added poisonous or deleterious substance found in the food supply. At the outset, this would encompass all of the substances, and all of the uses specified, in the current FDA action levels reprinted in Appendix A.

This would, however, only be the beginning. Many of the poisonous or deleterious substances listed in Appendix A can readily be found, under modern methods of analytical chemistry, in other foods as well. And as analytical methods become increasingly more sensitive, they will be found in still other food products.

Nor would this be the end of the matter. There are hundreds of other added poisonous or deleterious substances presently found in the food supply, under sensitive detection methodology, which present such an insignificant risk that FDA has not bothered to list them or to establish an action level. Under the extreme interpretation of the court of appeals, however, FDA would be required to establish a formal tolerance even for these substances, to avoid the food becoming unlawful *per se*.

Nor would even this finish the job. Dozens of natural food substances can be found, under extreme conditions of laboratory testing, to be carcinogenic, teratogenic,. or otherwise to produce toxic results. FDA presently concludes that the use of these substances should not be banned under Section 402(a)(1) and need not be limited under Section 406. The court of appeals would require a lengthy rulemaking for each.

All of this would be required solely in the name of strict statutory construction, with no attention paid to the overall statutory structure or to the protection of the public health. Scarce agency and industry resources would be channeled away from productive enterprise into formal rulemaking proceedings designed solely to satisfy procedural requirements. Formal rulemaking on a record, which is subject to the strict requirements for adjudication under the Administrative Procedure Act,[53] is resource-intensive and imposes substantial burdens upon FDA and the regulated industry.[54] There has been, and can be, no suggestion that any of these proceedings would advance public health objectives.

To the extent that any person believes that a current FDA action level is too high (or too low), or that a particular poisonous or deleterious substance that currently has no action level should in fact be regulated through an action level, procedural remedies are presently available. FDA has promulgated regulations establishing the right of any person to petition FDA for appropriate action under these circumstances.[55] There is no need to establish an entire new regulatory scheme in order to assure adequate protection both of the procedural rights of interested persons and of the substantive right to a safe food supply.

IV. The Decision of the Court of Appeals Conflicts With Two Authoritative Supreme Court Decisions.

The decision of the court of appeals in this case is fundamentally in conflict with two major Supreme Court de-

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[53]5 U.S.C. § 556 and § 557.

[54]*See, e.g.*, Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972). The enormous administrative burden that would have been imposed by the requirement of hundreds of such formal administrative hearings was one factor that led this Court to conclude that the FD&C Act should not be interpreted to incorporate such a requirement for all new drug application withdrawals in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 621 (1973).

[55]21 C.F.R. § 109.5 and § 10.30.

cisions, one of which was decided less than a week after the decision by the court of appeals in this case.

A. The Lexington Mill Decision Establishes FDA's Court Enforcement Authority Under Section 402(a)(1).

As noted above, the prohibition against added poisonous or deleterious substances under the 1906 Act, as interpreted by this Court in the *Lexington Mill* case in 1914, was explicitly retained by Congress under the 1938 Act.[56] Thus, Congress intended FDA to continue to exercise its administrative enforcement discretion to determine whether it was reasonably possible that an added poisonous or deleterious substance would render food injurious to health under actual conditions of use. There is no legislative history to support the view, advanced by the court of appeals, that enactment of Section 406 qualified or overruled this independent court enforcement authority.[57]

B. The Decision in *Heckler* v. *Chaney* Establishes That An FDA Administrative Determination Not To Initiate Court Enforcement Action Is Ordinarily Unreviewable In The Courts.

Just six days after the court of appeals handed down its decision in the instant case, the Supreme Court handed

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[56]Notes 12-14 *supra* and accompanying text.

[57]This Court has, in an analogous context, recognized that FDA has been given two independent methods of enforcing a common statutory objective—administrative rulemaking proceedings and direct action in the courts. In Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973), and CIBA Corp. v. Weinberger, 412 U.S. 640, 643-644 (1973), the Court held that FDA has primary jurisdiction to decide with administrative finality the regulatory status of products within its jurisdiction and, at the same time, independently has administrative discretion to initiate enforcement action directly in the courts. The CIBA decision explicitly recognized the power of FDA to initiate court enforcement action without first undertaking an administrative proceeding. The same logic applies here as well. Thus, the provisions of Section 406, relating to administrative proceedings, should in no way interfere with the provisions of Section 402(a)(1) authorizing court enforcement proceedings.

down its decision in *Heckler* v. *Chaney*.[58] It is apparent that the decision of the court of appeals is in serious conflict with the *Chaney* decision.

In *Chaney*, the Court held that an FDA decision not to initiate court enforcement action is ordinarily unreviewable in the courts. Absent fraud or other extraordinary circumstances, enforcement decisions are "committed to agency discretion" under the Administrative Procedure Act. In its opinion, the Court explained some of the "administrative concerns" which underlie this policy.[59] These "administrative concerns" describe, of course, the very reasons why FDA enforcement of the food safety provisions of the law must remain within the scope of administrative discretion.

The decision of the court of appeals, however, takes the matter entirely out of FDA's administrative discretion and requires the agency to establish formal tolerances, through rulemaking on a record, for each and every poisonous or deleterious substance found in the food supply. Under the interpretation adopted by the court of appeals, FDA's deployment of resources, and ordering of priorities, would be dictated by procedures imposed by the judiciary and not by public health concerns. They would be required for purely procedural rather than substantive reasons. The approach adopted by the court of appeals is thus irreconcilable with the approach of this Court in *Chaney*.

Even if formal tolerances were adopted for all poisonous or deleterious substances under Section 406, the *Chaney* decision would make them a procedural nicety and a substantive nullity. Enforcement priorities would remain discretionary with FDA regardless of the procedure imposed upon FDA in establishing unacceptable levels of poisonous or deleterious substances in the food supply. It makes little sense to reorder FDA's priorities, and to abrogate a well-established food safety regulatory program that has stood

[58]Heckler v. Chaney, 105 S. Ct. 1649 (1985).

[59]*Id.* at 1656.

the test of 50 years of experience, when the end result will be no different than it is now.

V. The Decision of the Court of Appeals Would Automatically Render the Vast Bulk of the American Food Supply Unlawful for the Foreseeable Future.

The action levels that would be invalidated by the court of appeals, as shown in Appendix A, pertain to a substantial portion of this country's food supply. Under the novel interpretation adopted by the court of appeals, all of the food covered by those action levels would instantly become adulterated and thus illegal *per se* under the FD&C Act. Equally important, all other foods which contain added poisonous or deleterious substances that FDA has determined to present only an insignificant risk, and thus do not justify even an action level, would be equally unlawful. With the extraordinary sensitivity of detection methodology now available to analytical chemists, it is difficult to imagine many foods, if any, that would escape this broad condemnation.

Even with heroic efforts and the deployment of a substantial portion of FDA personnel, it is unlikely that administrative proceedings could be initiated and completed for all of these added poisonous or deleterious substances in all of the myriad foods that comprise our national diet.[60] It is likely that, as soon as one proceeding was completed, other added poisonous or deleterious substances would be detected in still other foods. It is thus questionable whether FDA could ever catch up with the problem, or would forever be chasing an unachievable administrative goal.

This regulatory dilemma only serves to underscore the impractical and unrealistic interpretation adopted by the court of appeals, and the sound policy reasons for the consistent administrative interpretation adopted by FDA of these provisions for the past 50 years. As this Court has recognized, the FD&C Act "is to be treated as a working instrument of government and not merely as a

[60]Note 54 *supra*.

collection of English words"[61] and thus must be given "a liberal construction consistent with the Act's overriding purpose to protect the public health."[62] A formalistic requirement of rigid Section 406 tolerances, after rulemaking on a record, will achieve no such purpose.

It is no comfort to the food industry that, under the *Chaney* decision, FDA undoubtedly would exercise its inherent administrative discretion not to initiate court enforcement action against the entire food supply or even those foods for which action levels have been established as shown in Appendix A. There are serious commercial implications that could flow from the decision of the court of appeals as well. Under the Uniform Commercial Code, food is sold subject to the implied warranties of merchantability and fitness for the intended purpose.[63] Food that is in violation of federal law could readily be regarded as in violation of these implied warranties. Accordingly, the decision by the court of appeals could jeopardize virtually all commercial transactions in the food industry. Those who sought a way to abrogate contracts for the sale of food would need to look no further than the decision of the court of appeals in the instant case.

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[61]United States v. Dotterweich, 320 U.S. 277, 280 (1943).

[62]United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

[63]Uniform Commercial Code § 2-314 and § 2-315.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed.

Respectfully submitted,

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February 7, 1986

APPENDIX A

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. This list is current as of September, 1982. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single *copies* of this booklet are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

Copies of the *Compliance Policy Guides* (CPG) referenced in the action level list may be obtained from:

Food and Drug Administration
Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-6310

Other *references* in the action level list are filed under Docket No. 77N-0166 for public viewing at:

Food and Drug Administration
Docket's Management Branch (HFA-305)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-1753

For further *assistance or information* contact:

Food and Drug Administration
Guidelines and Compliance Research Branch
Bureau of Foods (HFF-312)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-3092

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FDA ACTION LEVELS

AFLATOXIN

Commodity	Action Level	Reference
Brazil nuts	20.0 mcgs/kg	CPG 7112.07
Feeds and feed ingredients	20.0 ppb	CPG 7126.33
Foods	20.0 mcgs/kg	CPG 7120.26
Milk	0.5 ppb (aflatoxin M_1)	CPG 7106.10
Peanuts & peanut products	20.0 mcgs/kg	CPG 7112.02
Pistachio nuts	20.0 mcgs/kg	CPG 7112.08

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.03 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

Commodity	Action Level	Reference
Animal feed, finished, processed	0.03 ppm	CPG 7126.27-A
Artichokes	0.05 ppm	CPG 7120.23-A
Eggs	0.03 ppm	CPG 7120.23-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	CPG 7126.27-A
Fish and shellfish	0.3 ppm	CPG 7120.23-A
Figs	0.05 ppm	CPG 7120.23-A
Hay (animal feed)	0.03 ppm	CPG 7126.27-A

Melons[1]	0.15 ppm	CPG 7120.23-A
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-A
Small fruits[1,2]	0.05 ppm	CPG 7120.23-A
Sugarbeet pulp (animal feed)	0.1 ppm	CPG 7126.27-A

[1]Other than those commodities specified in 40 C.F.R 180.135 and 180.137.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-B
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Barley, grain (human food)	0.1 ppm	CPG 7120.23-B
Beans	0.5 ppm	CPG 7120.23-B
Citrus fruit[2]	0.5 ppm	CPG 7120.23-B
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-B
Corn, fresh sweet	0.5 ppm	CPG 7120.23-B
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Corn, grain (human food)	0.1 ppm	CPG 7120.23-B
Eggs	0.5 ppm	CPG 7120.23-B
Endive	0.5 ppm	CPG 7120.23-B
Figs	0.5 ppm	CPG 7120.23-B
Frog legs	0.5 ppm	CPG 7120.23-B
Guavas	0.5 ppm	CPG 7120.23-B
Hays (animal feed)	0.1 ppm	CPG 7126.27-B
Mangoes	0.5 ppm	CPG 7120.23-B
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-B
Milo, sorghums (animal feed)	0.1 ppm	CPG 7126.27-B
Milo, sorghums (human food)	0.1 ppm	CPG 7120.23-B
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-B

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Oats, grain (human food)	0.1 ppm	CPG 7120.23-B
Peas	0.5 ppm	CPG 7120.23-B
Pineapples	0.5 ppm	CPG 7120.23-B
Quinces	0.5 ppm	CPG 7120.23-B
Root vegetables[2]	0.5 ppm	CPG 7120.23-B
Rice, grain	0.1 ppm	CPG 7120.23-B
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Rye, grain (human food)	0.1 ppm	CPG 7120.23-B
Small fruits[1],[2]	0.5 ppm	CPG 7120.23-B
Turnip greens	0.5 ppm	CPG 7120.23-B
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-B

[1]Other than those commodities specified in 40 C.F.R. 180.146.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

CADMIUM

Commodity	Action Level	Reference
Pottery(ceramics)		CPG 7117.06
Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	0.5 mcgs/ml of leaching solution	CPG 7117.06
Large hollowware (any one of 6 units)	0.25 mcgs/ml of leaching solution	CPG 7117.06

CHLORDANE

Commodity	Action Level	Reference
Animal fat, rendered	0.8 ppm	CPG 7126.27-C
Animal feed	0.1 ppm	CPG 7126.27-C
Fish	0.3 ppm	CPG 7120.23-C

CROTALARIA SEEDS
(C. spectabilis and/or C. sagittalis and/or C. striata)

Commodity	Action Level	Reference
Grains and Feeds	Average of 1 whole seed/pound	CPG 7126.15

FDA ACTION LEVELS

DIBROMOCHLOROPROPANE (DBCP)

Commodity	Action Level	Reference
Milk	1.5 ppm (fat basis)	CPG 7120.23-E
Raw agricultural commodities (except milk)	0.05 ppm	CPG 7120.23-E

DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-D
Barley, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Barley, grain (human food)	0.5 ppm	CPG 7120.23-D
Cocoa beans, whole raw bean	2.0 ppm	CPG 7120.23-D
Corn, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Corn, grain (human food)	0.5 ppm	CPG 7120.23-D
Eggs	1.5 ppm	CPG 7120.23-D
Fish	5.0 ppm	CPG 7120.23-D
Hay	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (animal feed)	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (human food)	0.5 ppm	CPG 7120.23-D
Oats, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Oats, grain (human food)	0.5 ppm	CPG 7120.23-D
Rice, grain (animal feed)	0.5 ppm	CPG 7126.27-D

Rice, grain (human food)	0.5 ppm	CPG 7120.23-D
Rye, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Rye, grain (human food)	0.5 ppm	CPG 7120.23-D
Wheat, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Wheat, grain (human food)	0.5 ppm	CPG 7120.23-D

FDA ACTION LEVELS

ENDRIN

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-E
Asparagus	0.05 ppm	CPG 7120.23-F
Beans	0.05 ppm	CPG 7120.23-F
Citrus fruits[2]	0.05 ppm	CPG 7120.23-F
Corn, fresh sweet	0.05 ppm	CPG 7120.23-F
Eggs	0.03 ppm	CPG 7120.23-F
Figs	0.05 ppm	CPG 7120.23-F
Fish and shellfish	0.3 ppm	CPG 7120.23-F
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	CPG 7126.27-E
Guavas	0.05 ppm	CPG 7120.23-F
Leafy vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Mangoes	0.05 ppm	CPG 7120.23-F
Melons	0.05 ppm	CPG 7120.23-F
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-F
Oilseed meal-peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	CPG 7126.27-E
Okra	0.05 ppm	CPG 7120.23-F
Peas	0.05 ppm	CPG 7120.23-F
Pimentoes	0.05 ppm	CPG 7120.23-F
Pineapples	0.05 ppm	CPG 7120.23-F
Pome fruits[2]	0.05 ppm	CPG 7120.23-F
Pumpkins	0.05 ppm	CPG 7120.23-F
Root vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Small fruits[2]	0.05 ppm	CPG 7120.23-F
Stone fruits[2]	0.05 ppm	CPG 7120.23-F

[1]Other than those commodities specified in 40 C.F.R. 180.131.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	CPG 7126.27-E

FDA ACTION LEVELS

FENTHION

Commodity	Action Level	Reference
Ground red peppers	0.3 ppm	CPG 7120.23-G

FDA ACTION LEVELS

HEPTACHLOR AND HEPTACHLOR EPOXIDE

The figures below are for residues of the above pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found at a level below 0.3 ppm for fish and 0.03 ppm for other products.

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-F
Artichokes	0.05 ppm	CPG 7120.23-H
Asparagus	0.05 ppm	CPG 7120.23-H
Beans, except snap beans	0.05 ppm	CPG 7120.23-H
Citrus fruits[2]	0.05 ppm	CPG 7120.23-H
Cucumbers	0.05 ppm	CPG 7120.23-H
Dairy products (manufactured)[1]	0.1 ppm	CPG 7120.23-H
Eggs	0.03 ppm	CPG 7120.23-H
Eggplant	0.05 ppm	CPG 7120.23-H
Figs	0.05 ppm	CPG 7120.23-H
Fish and shellfish	0.3 ppm	CPG 7120.23-H
Leafy vegetables	0.05 ppm	CPG 7120.23-H
Hays[1]	0.03 ppm	CPG 7126.27-F
Melons	0.05 ppm	CPG 7120.23-H
Okra	0.05 ppm	CPG 7120.23-H
Pears	0.05 ppm	CPG 7120.23-H
Pimentoes	0.05 ppm	CPG 7120.23-H
Pumpkins	0.05 ppm	CPG 7120.23-H
Quinces	0.05 ppm	CPG 7120.23-H
Rice, grain, (animal feed)	0.03 ppm	CPG 7126.27-F
Rice, grain (human food)	0.03 ppm	CPG 7120.23-H
Small fruits[1],[2]	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Stone fruits[1],[2]	0.05 ppm	CPG 7120.23-H
Squash (summer or winter)	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

KELTHANE
[1,1 Bis (p-chlorophenyl)-2,2,2-trichloroethanol]

Commodity	Action Level	Reference
Animal feed, finished processed	0.5 ppm	CPG 7126.27-H

KEPONE
[Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]

Commodity	Action Level	Reference
Crabmeat	0.4 ppm	CPG 7120.23-I
Fish	0.3 ppm	CPG 7120.23-I
Shellfish	0.3 ppm	CPG 7120.23-I

FDA ACTION LEVELS

LEAD

Commodity	Action Level	Reference
Pottery (ceramics)		CPG 7117.07
Flatware (ave. of 6 units)	7.0 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	5.0 mcgs/ml of leaching solution	CPG 7117.07
Large hollowware (any one of 6 units)	2.5 mcgs/ml of leaching solution	CPG 7117.07
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	CPG 7117.05
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	CPG 7117.05

FDA ACTION LEVELS

LINDANE

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-H
Artichokes	0.5 ppm	CPG 7120.23-J
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Barley (human food)	0.1 ppm	CPG 7120.23-J
Beans	0.5 ppm	CPG 7120.23-J
Citrus fruit[2]	0.5 ppm	CPG 7120.23-J
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-J
Corn, fresh sweet	0.5 ppm	CPG 7120.23-J
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Corn, grain (human food)	0.1 ppm	CPG 7120.23-J
Eggs	0.5 ppm	CPG 7120.23-J
Endive	0.5 ppm	CPG 7120.23-J
Figs	0.5 ppm	CPG 7120.23-J
Hays	0.1 ppm	CPG 7126.27-H
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-J
Milo (sorghum), grain (animal feed)	0.1 ppm	CPG 7126.27-H
Milo (sorghum), grain, (human food)	0.1 ppm	CPG 7120.23-J
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Oats, grain (human food)	0.1 ppm	CPG 7120.23-J
Peas	0.5 ppm	CPG 7120.23-J
Rice, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rice, grain (human food)	0.1 ppm	CPG 7120.23-J
Root vegetables[1],[2]	0.5 ppm	CPG 7120.23-J
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rye, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Small fruits[1],[2]	0.5 ppm	CPG 7120.23-J
Turnip greens	0.5 ppm	CPG 7120.23-J
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

MERCURY

Commodity	Action Level	Reference
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed.	1.0 ppm	CPG 7108.07
Wheat (pink kernals only)	1.0 ppm	CPG 7104.05

METHYL ALCOHOL

Commodity	Action Level	Reference
Imported brandy	0.35%	CPG 7119.09

MIREX

Commodity	Action Level	Reference
Fish	0.1 ppm	CPG 7120.23-K

NITROSODIMETHYLAMINE (NDMA)

Commodity	Action Level	Reference
Barley Malt	10 ppb	CPG 7104.07
Malt Beverages	5 ppb	CPG 7101.07

FDA ACTION LEVELS

PARALYTIC SHELLFISH TOXIN

Commodity	Action Level	Reference
Clams (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Mussels (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Oysters (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20

POLYBROMINATED BIPHENYLS (PBB's)

Commodity	Action Level	Reference
Milk & dairy products (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA Action Levels for Polybrominated Biphenyls (PBB) in Food", July 27, 1977
Meat (fat basis)	0.3 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

FDA ACTION LEVELS

POLYCHLORINATED BIPHENYLS (PCB's)

Commodity	Action Level	Reference
Paper food-packaging material intended for or used with human food, finished animal feed and components intended for animal feeds	10 ppm	21 CFR 109.30 (a)(9) and 509.30 (a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.03

TOXAPHENE

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-I
Artichokes	1.0 ppm	CPG 7120.23-L
Asparagus	1.0 ppm	CPG 7120.23-L
Cherries	1.0 ppm	CPG 7120.23-L
Figs	1.0 ppm	CPG 7120.23-L
Fish	5.0 ppm	CPG 7120.23-L
Melons	1.0 ppm	CPG 7120.23-L
Mustard greens	1.0 ppm	CPG 7120.23-L
Plums	1.0 ppm	CPG 7120.23-L
Pumpkins	1.0 ppm	CPG 7120.23-L
Root vegetables[1],[2]	1.0 ppm	CPG 7120.23-L
Small fruits[1],[2]	1.0 ppm	CPG 7120.23-L

[1]Other than those commodities specified in 40 C.F.R. 180.138.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Squash (summer or winter)	1.0 ppm	CPG 7120.23-L
Turnip greens	1.0 ppm	CPG 7120.23-L